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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,187	07/30/2003	Jurgen Engel	103832-477-NP	9817
7590 07/29/2005 GOODWIN PROCTER LLP 599 Lexington Avenue New York, NY 10022			EXAMINER DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,187

Applicant(s)

ENGEL ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to applicant's amendment received May 3, 2005.

Claims 1-12 are currently pending.

The previous objection of claims 5-6 under 37 CFR 1.75(c) set forth in paragraph 1 of the office action mailed Nov. 3, 2004 is withdrawn. However, claims 7-11 remain objected to under 37 CFR 1.75(c) because a multiple dependent claim cannot depend from another multiple dependent claims and should refer to other claims in the alternative only, i.e. —or—instead of “and.”

Claims 7-11 remain withdrawn from consideration.

The previous claim objection of claims 1-4, 12 set forth in paragraph 2 of the office action mailed Nov. 3, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, second paragraph, set forth in paragraph 3 of the office action mailed Nov. 3, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments traversing (1) the previous claim rejection under 35 USC 102(b) over Nickel et al., 6,093,704 (paragraph 4 of the office action mailed Nov. 3, 2004); (2) the previous claim rejection under 35 USC 102(e) over Nickel et al., 6,696,428 (paragraph 5 of the office action mailed Nov. 3, 2004); (3) the previous claim rejection under 35 USC 102(b) over Nossner et al., 6,172,050 (paragraph 6 of the office action mailed Nov. 3, 2004); (4) the previous claim rejection under 35 USC 103(a) over Engel et al., 5,942,639 in view of Nickel et al. (paragraph 7 of the office action mailed

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Nov. 3, 2004); and (5) the previous obviousness-type double patenting rejections set forth in paragraphs 8-9 of the office action mailed Nov. 3, 2004, have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Nov. 3, 2004 with the following additional comment:

Claim Rejection(s)—35 USC 102:

Applicant argues that Nickel et al. '704, '428 and Nossner et al. '050 fail to teach or suggest, either implicitly or explicitly, each and every element of the claimed invention. The scope of the presently claimed invention is the administration of the expressly claimed alkylphosphocholines in combination with the claimed anti-tumor medicaments for treating benign and malignant tumor diseases. None of the references discloses applicant's claimed combination.

Said arguments have been considered but are not found to be persuasive.

The examiner respectfully submits that applicant's arguments pertain to the intended use of the claimed drug products as well as the claimed method of using alkylphosphocholine compounds (formula (I) and (II)) for making a drug product to be used in a combination treatment method. Please note, applicant's claims are directed to a method of using the claimed alkylphosphocholine compounds "for the manufacture of a drug product for the treatment of benign oncoses before and/or during treatment" with the claimed anti-tumor substances. Claim 12 is drawn to a drug product comprising an alkylphosphocholine of formula I or II "for use in the treatment of benign and malignant oncoses with an approved antitumor substance."

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However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.). In this case, concerning claims 1-6, the intended use of treating benign and malignant oncoses before and/or during treatment with the claimed anti-tumor agents is of no significant to the method of using the claimed alkylphosphocholine compounds for the manufacture of a drug product. Finally, concerning claim 12, the pharmaceutical compositions disclosed by Nickel et al. '704, '428 and Nossner would be capable of performing the claimed intended use, i.e. for use in the treatment benign and malignant oncoses before and/or during treatment with the claimed anti-tumor agents.

Please note, claims 5-6 fall under the previous 102 rejections since they further limit the intended use of the claims from which they depend and therefore do not describe a structural difference between the claims and the prior art.

The rejections are respectfully maintained.

Claim Rejection(s)—35 USC 103:

Applicant argues that the prior art fails to disclose or fairly teach the claimed inventions. Specifically, there is no suggestion or motivation to use alkylphosphocholines in combination with the claimed anti-tumor substances. Furthermore, Nickel et al. '704 describe compositions and methods of using alkylphosphocholines in conjunction with an appetite-stimulating dopamine receptor antagonist to treat side effects of a decrease in body weight caused by administration of alkylphosphocholines in tumor therapy.

Said arguments have been considered but are not found to be persuasive.

As stated above, applicant's arguments pertain to the intended use of the claimed drug products as well as the claimed method of using alkylphosphocholine compounds (formula (I) and (II)) for making a drug product to be used in a combination treatment method. Applicant's claims are directed to a method of using the claimed alkylphosphocholine compounds "for the manufacture of a drug product for the treatment of benign oncoses before and/or during treatment" with the claimed anti-tumor substances. Claim 12 is drawn to a drug product comprising an alkylphosphocholine of formula I or II "for use in the treatment of benign and malignant oncoses with an approved antitumor substance."

However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as

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compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.). In this case, concerning claims 1-2, 5-6, the intended use of treating benign and malignant oncoses before and/or during treatment with the claimed anti-tumor agents is of no significant to the method of using the claimed alkylphosphocholine compounds for the manufacture of a drug product. Finally, concerning claim 12, the pharmaceutical compositions disclosed by Engel and Nickel et al. '704 would be capable of performing the claimed intended use, i.e. for use in the treatment benign and malignant oncoses before and/or during treatment with the claimed anti-tumor agents.

Please note, claims 5-6 fall under the previous 103 rejection since they further limit the intended use of the claims from which they depend and therefore do not describe a structural difference between the claims and the prior art.

The rejection is respectfully maintained.

Double Patenting Rejections:

Applicant essentially argues that the examiner has failed to make a prima facie case of obviousness regarding the use of alkylphosphocholines in combination with the anti-tumor medicaments for treating benign and malignant tumor diseases.

Said argument has been considered but is not found persuasive.

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For the same reasons discussed above as well as those presented in the office action mailed Nov. 3, 2004, the double patenting rejections are maintained.

Conclusion

Claims 1-6 and 12 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone

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number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

July 25, 2005

Rebecca Cook
REBECCA COOK
PRIMARY EXAMINER
GROUP 1200/1614